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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,964	07/15/2003	Satoshi Wada	029650-142	5917
7590 03/13/2007 BURNS, DOANE, SWECKER & MATHIS, L.L.P P.O. Box 1404			EXAMINER  JACKSON, BRANDON LEE	
			3772	
SHOPTENED STATITOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVED	VMODE
SHORTENED STATUTOR	T LEWIOD OF KESLONSE	MAIL DATE	DELIVERY MODE	
3 MO	NTHS	03/13/2007	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
	10/618,964	WADA ET AL.				
Office Action Summary	Examiner	Art Unit				
	Brandon Jackson	3772				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 22 Fe	hruary 2007					
	action is non-final.					
<i>;</i>						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
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Disposition of Claims	• .					
4) Claim(s) <u>1-28</u> is/are pending in the application.						
4a) Of the above claim(s) <u>21-28</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-20</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>15 July 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
Paper No(s)/Mail Date  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application						
Paper No(s)/Mail Date 10/17/03, 6/14/04, 3/25/04. 6) Other:						

### **DETAILED ACTION**

### Election/Restrictions

Applicant's election with traverse of Species I in the reply filed on 02/09/2007 is acknowledged. The traversal is on the ground(s) that all of the claims of this application can be examined at the same time without serious burden. This is not found persuasive because Applicant is only entitled to one invention per application, therefore the restriction is valid because the application contains more than one patentable species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species II-IV, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/09/2007.

## **Priority**

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

## Claim Objections

Application/Control Number: 10/618,964

Art Unit: 3772

Claim 1 is objected to because of the following informalities: "main" should precede balloon in the last 2 lines claim 1. Appropriate correction is required.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itonaga et al. (U.S. Patent 6,336,901) in view of Fareed (U.S. Patent 5,295,951). Itonaga discloses a cuff device (30) comprising a flexible band (13) that is adapted to or is capable of being wrapped around a limb (1) where bleeding is to be stopped (col. 6, lines 58-59), a hook and loop fastener liner that is a means for (col. 6, lines 16-17) securing the band in a wrapped stated, a main balloon (11) that inflates (col. 6, lines 33-35) when fluid is introduced therein, a pressing member (12) that

Application/Control Number: 10/618,964

Art Unit: 3772

overlaps the main balloon (11). The pressing member (12) presses against the main balloon (11) substantially towards the middle of the limb (1). The pressing member (12) is a secondary balloon (col. 6, lines 6-7) that presses against the main balloon (11) under the influence of pressure by the fluid. The pressing member (12) inflates (col. 6, lines 38-40) with the introduction of fluid therein. The pressing member (12) and the main balloon (11) have three-way cock system (61) for communication (figs. 7A-7C). The pressing member (12) and main balloon (11) are positioned near one end of the curved plate (fig. 3). The main balloon can also be positioned near the center portion of the top of the flexible band (13) and have a smaller radius of curvature (fig. 2). The main balloon (11) and the pressing member (12) are only connected on one side of the band (figs. 1-4). The term "connected" has been given its broadest, most reasonable definition; which is to be joined together through contact. With respect to claims 15, 18, and 20, these limitations are intended use and the Itonaga device (30) would be capable to perform the functions of decreasing pressure or deformation over intervals of time to certain inflation percentages. Itonaga fails to disclose a curved plate having an inner peripheral side, where the plate is made of a material more rigid than the band. However, Fareed discloses a band (50) with a curved plate (56) having an inner peripheral (fig. 5) and being inflexible (col. 4, lines 41-43), an inflatable balloon (55), and the ability to apply pressure to a limb (fig. 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Itonaga cuff (30)

to have a curved plate, as taught by Fareed, in order to provide transaxial counter

Art Unit: 3772

compression to the limb and prevent movement of the pressing member and main balloon.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itonaga et al. (U.S. Patent 6,336,901) in view of Fareed (U.S. Patent 5,295,951), further in view of Yamakoshi et al. (U.S. Patent 6,694,821). Itonaga/Fareed substantially discloses the claimed invention, see claim 1 rejection above. Itonaga/Fareed fails to disclose that the pressing member is smaller than the main balloon. However, Yamakoshi teaches a cuff (10) with a pressing member (14) smaller than the main balloon (16). Therefore, it would have been obvious to one of ordinary skill in the art to modify the pressing balloon of the Itonaga/Fareed device to make the member smaller than the main balloon in order to apply pressure towards the artery rather than the whole limb.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itonaga et al. (U.S. Patent 6,336,901). Itonaga substantially discloses the claimed invention, see claim 15 rejection above. Itonaga fails to disclose a tensile modulus of at most 10 gf/mm<sup>2</sup>. However, Applicant does not disclose that a tensile modulus of at most 10 gf/mm<sup>2</sup> solves any stated problem or provide any specific advantage; therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the Itonaga device of a material with a tensile modulus at the most 10 gf/mm<sup>2</sup>. The specified tensile modulus is a mere design consideration and does not patentably distinguish the claimed invention.

### Conclusion

Art Unit: 3772

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blessinger (U.S. Patent 4,920,971), Johnson et al. (U.S. Patent 5,496,262), Daneshvar (U.S. Patent 5,643,315), Kuroshaki et al. (U.S. Patent 5,66,182), Harren et al. (U.S. Patent 6,007,562), Itonaga et al. (U.S. Patent 6,527,727), Buckman (U.S. Patent Publication 2003/0199922).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson Examiner Art Unit 3772

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3/5/07